NOV 1 0 2003

K031385

# 510(k) Summary

# AZ-733-V Respiratory Gating System

Common/Classification Name: Radiographic ECG/Respiratory Synchronizer
21 CFR 892.1970

Anzai Medical Company, Ltd.
3-6-25 Nishi-Shinagawa
Shinagawa-ku
Tokyo 141-0033
Japan

Contact: T. Kaneko, Prepared: April 28, 2003

## A. LEGALLY MARKETED PREDICATE DEVICES

The **AZ-733 Respiratory Gating System** is substantially equivalent to the Varian RPM Respiratory Gating System, which was cleared for marketing by FDA on June 8, 1999 under K983629.

## B. DEVICE DESCRIPTION

The AZ-733 Respiratory Gating System system employs a respiratory sensor which can be fixed directly to or nearly to a patient, and detects the respiratory motion changes according to the type of sensor, a load cell (standard) or laser sensor (optional).

The Load Cell detects the mechanical expansion of the thoracic cavity resulting from the respiratory motion as the pressure changes of up/downward movement of the chest and abdomen. The Laser Sensor detects the distance change to the chest surface with the expansion of the thoracic cavity resulting from the respiratory motion of the chest and abdomen.

The analog signals from the Respiratory Sensor are detected and transmitted to the Sensor Port. There those signals are amplified, converted into digital form, and then output through a cable to the Wave Deck. The Wave Deck processes the signals, changing them into serial format for transmission to the Personal Computer. The Personal Computer monitors the respiratory signals all the time and commands the Wave Deck to output the gating signals when those respiratory signals reach the preset phase of respiration. Those gating (TTL) signals are transmitted to diagnostic imaging apparatus like X-ray CT or radiation

therapy equipment. K031385

## C. INTENDED USE

The AZ-733 Respiratory Gating System is intended to be used with diagnostic x-ray or radiation therapy systems to gate these devices on and off when target points of the patient's respiratory cycle are within preset limits.

## D. SUBSTANTIAL EQUIVALENCE SUMMARY

The AZ-733 Respiratory Gating System has similar, but not identical, indications for use as the currently marketed Varian RPM Respiratory Gating System. The differences relate only to the specific characteristics of each device and do not change the intended diagnostic or therapeutic effect. The devices clearly have the same intended use-the gating of radiation therapy devices through analysis of respiratory waveforms from the patient. The AZ-733 Respiratory Gating System has the "same technological characteristics" as the currently marketed Varian RPM device. The descriptive characteristics are sufficiently precise to assure substantial equivalence except in a few cases where performance data are provided. A comparison of these characteristics demonstrates substantial equivalence.[1]

## E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the sensors of the AZ-733 is somewhat different from the predicate device. The processing of the detected signals uses very similar technology.

The sensor of the AZ-733 can be either a strain gauge or a laser sensor. The predicate device uses a video camera and image processing to follow movement.

## F. TESTING

The device has been designed to the requirements of the EN-60601-1-1 for electrical safety and EN-60601-1-2 for electromagnetic compatibility. Testing is currently under way and the device will not be marketed in the U.S. until the testing has been successfully completed.

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[1] The meaning of the terms "substantial equivalence" and "substantially equivalent" as used in this 510(k) is limited to the way they are defined in, and used by FDA in accordance with, Sections 513(f)(1) and 513(l)(1) of the Federal Food, Drug, and Cosmetic Act.

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## G. CONCLUSIONS

This pre-market notification has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Anzai Medical Co., Ltd.
% T. Whit Athey, Ph.D.
Senior Consultant
The Health Policy Resources Group, LLC
2305 Gold Mine Road, Suite 200
BROOKVILLE MD 20833-2233

Re: K031385
Trade/Device Name: AZ-733 Respiratory Gating System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 LHN
Dated: October 2, 2003
Received: October 2, 2003

Dear Dr. Athey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K031385

Device Name: AZ-733 Respiratory Gating System

Indications For Use:

The AZ-733 Respiratory Gating System is intended to be used with diagnostic x-ray or radiation therapy systems to gate these devices on and off when target points of the patient's respiratory cycle are within preset limits.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031385

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